Establishment Inspection Report	FEI:	**3006791331**
MEDRAD, Inc. (Saxonburg Plant) dba Bayer R&I	EI Start:	08/06/2013
Saxonburg, PA 16056-9772	EI End:	08/07/2013

SUMMARY OF FINDINGS

Inspection of this manufacturer of class II medical devices was conducted as a routine FY13 work plan assignment (FACTS #8690859). This was a level II QSIT inspection covering subsystems / activities applicable to this site, conducted per CP 7382.845 and FDA's *Guide to Inspection of Quality Systems*. The Saxonburg plant is engaged in manufacture of sterile disposables (syringes / administrations sets) for Medrad /Bayer R&I's *Stellant* family of CT injectors. The previous FDA inspection of this site in early 2011 was classified NAI.

Upon arrival we presented credentials and a NOI to Mr. Peter K. Ochel, Site Manager, who is reportedly responsible for the day to day operations of the Saxonburg plant. Inspection and interview revealed that this facility continues to engage in largely automated assembly and pre-sterile packaging of syringes and administration sets for Medrad's CT injectors. Syringe assembly and kit packaging occurs in a clean room (b) (4) environment. This site also performs incoming acceptance testing of *Avanta* (CV injector) administration set batches. Annual sales volume associated with products produced at this site are estimated at $ (b) (4) . Terminal sterilization by e-beam occurs at an adjacent (b) (4) site, which is physically connected to the inspected facility. The current inspection was the second of three inter-related inspections of local Medrad producing facilities, the others being E-M assembly (Heilman Center) in Harmarville, and the Friel Center (910 plant) in Indianola. The Saxonburg site reported upon herein shares a quality management system and M.I.S. with the other two sites.

History, processes and jurisdictional issues have been addressed in previous EIRs and are largely unchanged. Mr. Sam Liang, Medrad CEO, continues to be the individual ultimately responsible for this site's operations. Other organizational structure information for Medrad /Bayer is documented in concurrent EIR of sister site.

This inspection covered Management Controls, CAPA and Production & Process controls as applicable to *Stellant* syringe assembly and sterile disposable kit packaging. Saxonburg site QA Director Mr. George Siddoway provided most of the information obtained. We reviewed procedures for and documentation of Management Review and audit activities for the plant and observed no problems. We reviewed CAPA activities associated with *Stellant* sterile disposables manufacturing including non-conformances (review and disposition), supply quality issues, complaints, environmental monitoring and formal CAPA actions, with no significant problems observed. We reviewed processes supporting incoming acceptance activities (for *Avanta* administration sets, for example) and found those operations to be suitably controlled and documented. We reviewed line set-up and clearance practices, as well as in-process and Finished Goods quality assurance activities. We found no significant deficiencies relative to the requirements of the QSR. Review of complaint processing activities specifically relating to *Stellant* sterile disposables revealed no objectionable conditions or practices. Review of observed visual inspection activities revealed operational personnel had appropriate training documented, and suitable visual standard references were available. No significant objectionable conditions or practices were observed, no FDA 483 was issued.

We advised site management that we would not be issuing an FDA 483, but intended to do a formal final close-out of all three sequential site inspections upon completion of our audit of the Indianola site (due to the inter-related nature of the inspections).

ADMINISTRATIVE DATA

Inspected firm:	MEDRAD, Inc. (Saxonburg Plant) dba Bayer R&I
Location:	150 Victory Rd Saxonburg, PA 16056-9772
Phone:	724-360-7602
FAX:	412-767-1282
Mailing address:	150 Victory Rd Saxonburg, PA 16056-9772
Dates of inspection:	8/6/2013, 8/7/2013
Days in the facility:	2
Participants:	James M. O'Donnell, Investigator Dennis Hock, Investigator

This was a team inspection conducted by Investigators Jake O'Donnell and Dennis Hock. Mr. O'Donnell wrote this report. No samples were collected.

Attachments:

1.) FDA 482 Notice of Inspection

James M. O'Donnell, Investigator

Dennis Hock, Investigator